Sanofi: Important Information on Plaquenil® and COVID-19

Bangladesh, 12 May– There has been increased media coverage around the off-label use of hydroxychloroquine in the management of COVID-19 based on preliminary results from independent studies from different countries. The situation is raising many questions from our different stakeholders.

Patient safety is the priority

To date there is insufficient clinical evidence to draw any conclusions over the clinical efficacy or safety of hydroxychloroquine (or chloroquine) in the management of COVID-19. The preliminary results from different independent studies require further analysis and more robust and larger clinical studies to assess the patient benefit/risk profile of Plaquenil® in COVID-19.

Today, in Bangladesh, Plaquenil® (hydroxychloroquine) is not registered. The product has been imported as donation based on special request from Ministry of Health (MoH) for COVID-19 pandemic. Plaquenil® (hydroxychloroquine) has been imported within the scope of 'Special Import License' authorized by Directorate General of Drug Administration (DGDA) in the context of COVID-19 management in the country. The product will be used according to the treatment guideline of MoH.

Any use of this medicine in the management of COVID-19 is an off-label use (i.e. in absence of a marketing authorization for the indication of COVID-19 even when national guidance/recommendations have been issued).

Ensure supply continuity

Sanofi is working with local health authorities and scientific experts in different countries impacted by the outbreak in order to investigate the patient benefit/risk profile of Plaquenil® (hydroxychloroquine) in the treatment of COVID-19 and, if requested by the local governments and / or health authorities, to provide the product to the extent that it can.

At their request, Sanofi donated 500,000 doses of hydroxychloroquine medicine to Bangladesh health authorities.

For medical information or questions: Please contact the Sanofi Medical Information Helpline from 9AM to 5PM on any working day (Office closed on Friday, Saturday and Public Holidays): 880-9678 400 900 or mail to medinfo.BD@sanofi.com

Please note that, Sanofi is following Bangladesh government's regulations for office opening during this COVID-19 situation. Hence the office will remain closed till the government circulated general holiday.

IMPORTANT SAFETY REMINDER ABOUT PLAQUENIL®

The main side effects of hydroxychloroquine are described in the product information. At the recommended daily dose for approved indications, ranging from 200 to 400 mg (without exceeding 600 mg at treatment onset) daily in adults for chronic treatment of autoimmune indications, or based on body weight (and without exceeding 1550 mg base in adults) in acute treatment of malaria, the most serious side effects of hydroxychloroquine are eye disorders following long term use, including retinopathy, with changes in pigmentation and visual field defects and severe hypoglycemia including loss of consciousness (in patients treated with and without antidiabetic medications). Cardiotoxic effects are rare but serious complications of hydroxychloroquine, which include acute cardiac conduction disorders (QT prolongation, ventricular arrhythmia) have also been observed. Neurological, hepatic, severe skin disorders, allergic reactions have also been described.

Hydroxychloroquine should be used with caution in patients receiving drugs known to prolong the QT interval such as some anti-infectives, e.g. macrolides including azithromycin, due to an increased risk of ventricular arrhythmia.

A significant number of serious and life-threatening cases of QT prolongation, torsade de pointe, syncope, cardiac arrest, and sudden death has been reported to Sanofi Global Pharmacovigilance in the context of Covid-19 management.

The risk and severity of side-effects may increase with a higher posology (dosage) of hydroxychloroquine.

Healthcare professionals should consult the current Summary of Product Characteristics for the most up to date safety information. Patients taking hydroxychloroquine-containing medicines, like any other medicines, should follow the instructions provided in the Patient Information Leaflet.

Patients must not take Plaquenil® without medical prescription or advice. They should always consult with their healthcare professionals.

Sanofi is asking local Health Authorities to communicate a clear position regarding current lack of robust clinical data for the use of Plaquenil®, in the management of COVID-19, emphasizing that such use will be off-label, and to communicate the known serious adverse reactions associated with Plaquenil®, namely the contraindications in patients with known hypersensitivity to 4-aminoquinoline compounds; with pre-existing maculopathy of the eye; below 6 years of age (200mg tablets not adapted for weight <35 kg) and the risk of retinal toxicity, hypoglycemia and cardiac toxicity as well as the known risk of interactions.

Sanofi also requests that all off-label use is communicated to the Sanofi affiliate pharmacovigilance team Bangladesh.Pharmacovigilance@sanofi.com or the national spontaneous reporting system, whether or not the patients suffer adverse events.